

### **REMARKS**

Reconsideration and withdrawal of the rejections set forth in the Office action dated August 28, 2001 are respectfully requested.

#### **I. Amendments**

Claim 1 is amended to include the limitation of claim 2, that the weight ratio of linoleic fatty acid to said  $\alpha$ -linolenic fatty acid in said composition is 0.05-2.0. Claim 2 is canceled accordingly.

Claim 6 is amended by incorporation of the contents of claim 5 and by amending the transition language to recite that the capsule consists essentially of linoleic fatty acid and  $\alpha$ -linolenic fatty acid in the recited ratio.

Claim 8 is amended by incorporation of the contents of claim 7 and by amending the transition language to recite that the oil consists essentially of linoleic fatty acid and  $\alpha$ -linolenic fatty acid in the recited ratio.

Claim 19 has been amended to the unsaturated fatty acid components and the weight ratio of these components in the food. Support for this amendment can be found, for example, in claim 2.

Claim 21 has been amended to clarify that the weight ratio of linoleic fatty acid to  $\alpha$ -linolenic fatty acid in the animal is 0.05 to 2.0. Support for this amendment can be found, for example, on page 4, lines 23-24.

Claims 23-25 are dependent claims directed to a method of preparing a foodstuff by adding the composition described in claims 2, 19 or 20. Basis for the claims can be found, for example, on page 6, lines 3-5 and page 4, lines 16-22.

Claims 26-29 are directed to an unsaturated fatty acid composition comprising flaxseed oil. Claims 30-33 are directed to a capsule comprising flaxseed oil. Claims 34-37 are directed to an edible oil comprising flaxseed oil. Claims 38-41 are directed to a dietary supplement comprising flaxseed oil. Claims 42-45 are directed to a foodstuff comprising flaxseed oil. Basis for these claims can be found on page 4, lines 9-20, page 5, lines 4-6 and 17-20, page 6, lines 3-6, and on page 7, lines 3-7.

By these amendments, no new subject matter has been added.

## II. Rejections under 35 U.S.C. §102

Claims 18-22 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Schmidl *et al.* (U.S. Patent No. 5,504,072).

Claims 1-2 and 18-22 were rejected under 35 U.S.C. §102(e) as allegedly anticipated by Igarashi (U.S. Patent No. 6,159,507).

These rejections are respectfully traversed.

### A. The Invention

The present invention, as embodied in claims 1 and 19-22 relates to a composition (claim 1), a food composition (claims 19, 20), or a dietary supplement (claims 21, 22) consisting essentially of linoleic acid and  $\alpha$ -linolenic acid in a ratio of 0.05 to 2.0.

### B. The Prior Art

SCHMIDL ET AL. describe an enteral nutritional composition that includes a lipid component comprised of 2-4% of the total calories omega-6 polyunsaturated fatty acids (linoleic acid) and 0.2-1.0% of the total calories omega-3 polyunsaturated fatty acids (linolenic acid). Thus, the ratio of omega-6:omega-3 is between 2 and 20.

IGARASHI describes a "balance modifier" that can be added to food in order to adjust the *in vivo* ratio of omega-6 unsaturated fatty acids to omega-3 unsaturated fatty acids.

### C. Legal Standard

According to the M.P.E.P. § 2131, "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference".

### D. Analysis of Rejection based on Schmidl *et al.*

As noted above, the invention as presently claimed is directed to a composition consisting essentially of linoleic acid and  $\alpha$ -linolenic acid in a ratio of 0.05 to 2.0.

Schmidl *et al.* fail to teach such a composition. In Schmidl *et al.* the omega-6 fatty acid to omega-3 fatty acid calorie ratio is described as "the lipid component preferably comprises omega-6 polyunsaturated fatty acids (i.e., linoleic acid) at 2-4% of total calories and omega-3 polyunsaturated fatty acids (i.e.,  $\alpha$ -linolenic acid) at 0.2-10% of total calories." (Col. 4, lines 26-29). Thus, Schmidl *et al.* teaches that the ratio of omega-6 polyunsaturated fatty acids to omega-3 polyunsaturated fatty acids is preferably between 2.0 and 20.0. Therefore, following the teaching of Schmidl *et al.* one skilled in the art would not arrive at the essential feature of the present invention – an omega-6 to omega-3 weight ratio of between 0.05 and 2.0.

Accordingly, Applicants submit that standard of strict identity to maintain a rejection under 35 U.S.C. §102 has not been met. Withdrawal of the rejection under 35 U.S.C. §102(b) is respectfully requested.

#### E. Analysis of Rejection based on Igarashi

Igarashi fails to teach a composition consisting essentially of linoleic fatty acid and  $\alpha$ -linolenic fatty acid. The composition of Igarashi comprises an active ingredient of a dioxabicyclo(3,3,0)octane derivative as a "balance modifier". It is clear that this balance modifier would have a material effect on the omega-6 to omega-3 ratio, since its sole function is to adjust the ratio of *in vivo* fatty acid lipids. Thus, the composition disclosed by Igarashi includes an element necessarily excluded by the present claims, that are now limited to a composition consisting essentially of omega-6:omega-3 fatty acids in a ratio of 0.05-2.0.

Moreover, none of the compositions described in the Examples of Igarashi teach the claimed omega-6:omega-3 fatty acid ratio of 0.05-2.0. In Example 1, Group 1 is fed a linoleic acid lipid composition with an omega-6:omega-3 ratio of 3. Group 3 is fed a linolenic acid composition with an omega-6 to omega-3 ratio of 0.33. Similarly, none of Examples 2-9 teach a food composition having an omega-6 to omega-3 ratio between 0.05-2.0. Therefore, the food compositions disclosed in Igarashi fail to teach an omega-6 to omega-3 ratio between 0.05-2.0.

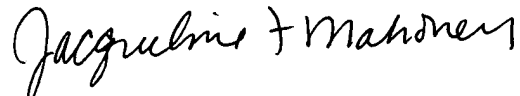
Accordingly, Applicants submit that standard of strict identity to maintain a rejection under 35 U.S.C. §102 has not been met. Withdrawal of the rejections under 35 U.S.C. §102(e) is respectfully requested.

III. Conclusion

In view of the foregoing, Applicants submit that the claims pending in the application patentably define over the prior art. A Notice of Allowance is therefore respectfully requested.

If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is encouraged to call the undersigned at (650) 838-4402.

Respectfully submitted,



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Appl. No. 09/499,693

**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

1. (Twice Amended) An unsaturated fatty acid composition consisting essentially of linoleic fatty acid (n-6, 18:2) and  $\alpha$ -linolenic fatty acid (n-3, 18-3) wherein the weight ratio of said linoleic fatty acid to said  $\alpha$ -linolenic fatty acid in said composition is [0.05-7.5] 0.05-2.0.

6. (Amended) [The]A capsule [as claimed in claim 5,] consisting essentially of linoleic fatty acid (n-6, 18:2) and  $\alpha$ -linolenic fatty acid (n-3, 18-3) wherein the weight ratio of said linoleic fatty acid to said  $\alpha$ -linolenic fatty acid in said capsule is 0.05-2.0.

8. (Amended) [The]An oil [as claimed in claim 7,] consisting essentially of linoleic fatty acid (n-6, 18:2) and  $\alpha$ -linolenic fatty acid (n-3, 18-3) wherein the weight ratio of said linoleic fatty acid to said  $\alpha$ -linolenic fatty acid in said oil is 0.05-2.0.

19. (Amended) A food comprising the unsaturated fatty acid composition as claimed in claim [18.]2, wherein the unsaturated fatty acid component of the food consists essentially of linoleic fatty acid (n-6, 18:2) and  $\alpha$ -linolenic fatty acid (n-3, 18-3), wherein the weight ratio of said linoleic fatty acid to said  $\alpha$ -linolenic fatty acid in said lipid component is 0.05-2.0.

21. (Amended) A dietary supplement consisting essentially of [ $\alpha$ -linolenic fatty acid (n-3, 18:3)] linoleic fatty acid (n-6, 18:2) and  $\alpha$ -linolenic fatty acid (n-3, 18-3) for administration to an animal such that the weight ratio of the daily supply of said linoleic fatty acid to said  $\alpha$ -linolenic fatty acid [to]in said animal is 0.05-[7.5]2.0.